UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF PUNAM KELLER, PH.D.

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Defendants' Executive Committee, on behalf of the undersigned Defendants, submits this response in opposition to Plaintiffs' *Daubert* Motion to Exclude Testimony of Punam Keller, Ph.D. [ECF No. 2041] ("Motion" or "Mot.").

INTRODUCTION

Punam Keller, Ph.D., a chaired professor at the Tuck School of Business at Dartmouth College, is one of the world's leading authorities on consumer behavior, with more than four decades of experience studying how consumers value health care products and services. A central question before the Court at the class certification stage is whether Plaintiffs can establish the elements of their claims, including questions of materiality, reliance, causation and damages, through common or classwide evidence. Dr. Keller's opinions regarding consumer behavior are directly relevant to these issues, including the flaws in Plaintiffs' fundamental theory: that all of Defendants' valsartan-containing drugs ("VCDs") were "worthless" to all purchasers.

Contrary to the arguments in Plaintiffs' Motion, Dr. Keller is highly qualified to opine on the economic value of VCDs to consumers, and she has supplied a reliable framework to address this question grounded in established principles of behavioral economics, an extensive body of literature, and abundant real-world evidence. Plaintiffs' arguments to exclude Dr. Keller's opinions amount to a series of mischaracterizations of her opinions, misquoted or out-of-context fragments of

her testimony to suggest "admissions" she has not made, and unsubstantiated attacks on her well-founded and reliable opinions. Essentially, Plaintiffs ask the Court to accept the opinions of their economist, Dr. Conti, and to exclude the opinions of Dr. Keller simply because she criticized her opinions. But Dr. Keller is highly qualified and has offered reliable opinions and testimony that fit the class certification stage of these proceedings. Plaintiffs' contrary arguments fail for four reasons.

First, Dr. Keller's opinions more than satisfy the standard of reliability. They are based on ample literature and empirical studies, as well as established principles of behavioral economics and observed consumer behavior. She further grounds her opinions in reliable examples demonstrating how real consumers assess risk and value. Plaintiffs' criticisms of Dr. Keller, on the other hand, both mischaracterize her supposed "assumptions" regarding consumer choice and seek to impose upon Dr. Keller a non-existent requirement to undertake new empirical research negating Plaintiffs' claims. The law is clear, however, that Dr. Keller is permitted to criticize Plaintiffs' theories based on existing data and literature, and Plaintiffs' criticisms at best go to the weight of her testimony, not its admissibility.

Second, the real-world evidence cited by Dr. Keller is reliable, including named Plaintiffs' own testimony admitting the efficacy and value of Defendants' medications, FDA's and physicians' guidance to continue taking Defendants' valsartan until they could obtain a replacement, and FDA's setting of acceptable

daily intake limits for nitrosamines. Plaintiffs simply try to assume away these facts by insisting they are irrelevant under Plaintiffs' theory of economic value—but that is the very theory Dr. Keller criticizes, and the evidence on which she relies is appropriate and reliable to support her criticisms.

Third, Dr. Keller has not made the "admissions" attributed to her by Plaintiffs and does not ignore facts relevant to her opinions regarding consumer behavior. The putative "admissions" elicited by Plaintiffs at Dr. Keller's deposition—pertaining to her lack of reliance upon post-recall ZHP sales data and her absence of opinions on federal laws and regulations—simply have nothing to do with the subject matter of her opinions and thus are unrelated to the admissibility of her opinions.

Fourth, Dr. Keller is well-qualified to critique Dr. Conti's economic opinions and, contrary to Plaintiffs' mischaracterizations, did not "affirm" Dr. Conti's opinions or conclusions. To the contrary, Dr. Keller vigorously critiques Dr. Conti.

For these reasons, the Court should deny Plaintiffs' Motion.

SUMMARY OF DR. KELLER'S OPINIONS

Dr. Keller holds a B.A. in Economics and Statistics from Bombay University in India, an M.B.A. in Marketing from the Bajaj Institute of Management at Bombay University, and a Ph.D. in Marketing from Northwestern University. (Exhibit A, curriculum vitae of Dr. Punam Keller). She is a chaired professor and Senior Associate Dean at the Tuck School of Business at Dartmouth College in Hanover,

New Hampshire, where she teaches marketing to both graduate and undergraduate students. (*Id.*; Expert Declaration of Punam Keller, Ph.D., dated January 12, 2022 (Mot., Exhibit 1)("Keller Rep.") ¶ 2). She is an expert with more than four decades of experience studying and teaching topics on consumer behavior, with a focus in health and financial well-being. (Keller Rep. ¶¶ 2-5).[1]

Dr. Keller offers opinions in this case about how consumers value products and how they assess new health information. Dr. Keller explains that consumers employ a variety of decision rules and approaches in the healthcare context, each depending on their individualized circumstances. The "compensatory decision-rule" is commonly used to understand healthcare decision-making, and "is an appropriate model to apply to assess the potential change in value to consumers, if any, following the recalls of certain VCDs." (*Id.* ¶ 8). Consumers applying the compensatory decision-rule in the context of prescription drugs assign different weights to different feature of the medications, and often place a higher value on one feature to compensate for a lesser value of another feature. (*Id.*) Consumers "continually make risk trade-offs when weighing the drug's costs and benefits." (*Id.*) By contrast, application of a "non-compensatory decision-rule," would result in a binary value

[1] Dr. Keller's full list of qualifications and experience, particularly in the realm of consumer health behavior, is laid out in full in her CV (attached as Exhibit A) and in her report (Mot., Ex. 1).

assessment (i.e., a "yes" (positive value) or "no" (negative value) on any one dimension). (*Id.*)

In assessing health decision making by consumers, Dr. Keller provides a framework that focuses on three key factors: (1) ***M****essage* (i.e., what information consumers receive), (2) ***I****ndividual characteristics* (i.e., unique medical history and health profiles), and (3) ***C****ontext* (i.e., physician trust and social norms), as well as the ***I****nteraction* of these three factors ("MICI"). (*Id.*) Viewing real world evidence through this framework reveals that, contrary to Dr. Conti's assertions, some consumers would place "significant value on the benefits" that they received from the VCDs that they purchased, which provided effective therapeutic treatment, while "other consumers would assess different levels of perceived or potential negative impact resulting from the impurities." (*Id.*) Dr. Keller concludes that, consistent with observed consumer behavior, "it is likely that a spectrum of consumer valuations would exist in this case given these varied assessments of the benefits of the at-issue VCDs and the risks perceived from the impurities." (*Id.*)

Dr. Keller's criticisms of Dr. Conti's opinions encompass two central points:

> (1) Dr. Conti implicitly relies on a uniform, non-compensatory decision-rule for calculating damages which assumes that the entirety of the value generated from the at-issue VCDs was destroyed by a single alleged feature—the potential presence of impurities—without considering other features such as therapeutic value; and
>
> (2) Dr. Conti's analysis is not consistent with the goal of determining potential economic damages to consumers because it ignores the fact

> that consumers did purchase the VCDs, and therefore it is more appropriate to utilize a downward shift in the demand curve to assess the potential impact of the nitrosamine impurities on consumers' retrospective valuations of Defendants' VCDs.

(*Id*. ¶ 9). Dr. Keller explains that Dr. Conti "ignores the inputs into the range of values that individuals may still assign to Defendants' VCDs," and applies the MICI factors in the context of Defendants' VCDs to demonstrate how consumer valuations of their VCDs are highly individualized. (Keller Rep. ¶ 35).

LEGAL STANDARD

The standards governing the admissibility of expert testimony are set forth in Defendants' Memorandum of Law in Opposition to the Motion to Partially Exclude Opinions of Defense Class Expert Timothy E. Kosty, and incorporated fully herein. As set forth below, Dr. Keller's opinions satisfy these standards and Plaintiffs have not offered any cognizable grounds for excluding her opinions.

ARGUMENT

I. DR. KELLER USED A RELIABLE METHODOLOGY IN FORMING HER OPINIONS.

Plaintiffs' criticisms of Dr. Keller's methodology are premised on a mischaracterization of her opinions as being based on a "hypothetical world" in which Dr. Keller assumes that consumers knew about VCD impurities at the time of purchase, were presented with a false "choice" between "contaminated" VCDs or no VCDs, and could have chosen to purchase impure VCDs. (Mot. 2-9). Plaintiffs

have it backwards. It is Dr. Conti's model that depends on a purely hypothetical world in which there was "no intersection of the supply and demand curves [for VCDs,] resulting in no economically determinable price" for the medications, which Plaintiffs conflate with an absence of economic value. (Mot. 15). In reality, as Dr. Keller explains, Defendants' VCDs ***were*** available for purchase, supply and demand curves intersected, prices were set, and consumers purchased and used Defendants' VCDs, realizing significant therapeutic benefits from them. Dr. Keller opines that, in these real-world circumstances, determining economic loss, if any, requires an understanding of how individual consumers respond to new information regarding product risks and how that response interacts with existing information to adjust their economic valuations. (*See* Keller Rep. ¶ 8). Contrary to Plaintiffs' assertions, Dr. Keller's opinions: (1) are reliably supported by numerous articles, empirical studies, and scholarly research that detail well-established principles of consumer behavior; (2) are grounded in reliable factual examples that demonstrate how real consumers assess risk and value; (3) do not turn on false or "hypothetical" assumptions regarding consumer choice; and (4) do not require a consumer survey or conjoint analysis.

A. Dr. Keller's Opinions Are Well-Supported By Literature And Empirical Studies, And Are Based On Established Tenets Of Behavioral Economics And Observed Consumer Behavior.

At the outset, Plaintiffs' Motion ignores the actual bases for Dr. Keller's

opinions and instead mischaracterizes them as "unsupported speculation." (Mot. 2). In fact, Dr. Keller's opinions are based on well-accepted tenets of behavioral economics regarding how individual consumers make decisions and perform value assessments as they weigh the factors most important to them. (Keller Rep. ¶¶ 21-26). Her opinions are supported by 48 published sources, including empirical studies, peer-reviewed literature, and research. (*See generally* Keller Rep.).

One of these 48 sources (and the *only* study Plaintiffs asked Dr. Keller about at her deposition) was an empirical study of physicians and consumers that asked the participants to rank certain topics of importance when initiating medical therapy.[2] (Exhibit B, Transcript of March 10, 2022 Deposition of Punam Keller ("Keller Dep."), 55:19-58:13). Participants ranked safety and efficacy, respectively, as the top two topics of importance. (Keller Rep., ¶ 26 n.36). When asked about this study, Dr. Keller explained that even though "safety" was the most common answer (given by 33 out of 108 consumer participants), it was significant that "what that means is basically 70-plus consumers did ***not*** rate safety as the most important topic during the initiation of medical therapy," demonstrating "a range of consumer responses as to the importance of specific features and the weight [ ] on those

[2] *See* Keller Rep., ¶ 26 n. 36 (discussing Schommer, Jon C., et al., *Decision-Making During Initiation of Medication Therapy*, Research in Social and Administrative Pharmacy, Vol. 10 (2), April 2014, pp. 313-327).

features." (Keller Dep. 56:19-57:2) (emphasis added).

It is beyond dispute (and Plaintiffs have not meaningfully argued otherwise) that Dr. Keller's opinions that consumers place different weights on various features when it comes to medications are supported by this study and the many other empirical studies and literature cited in her report, and are not based "on subjective belief or unsupported speculation." *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). Plaintiffs' characterization of Dr. Keller's opinions as "unsupported speculation" or "unreliable" therefore falls flat.[3]

B. Dr. Keller's Opinions Are Grounded In Reliable Examples That Demonstrate How Real Consumers Assess Risk And Value.

Plaintiffs also argue that Dr. Keller's opinions stem from an "outright false factual assumption" that consumers were able to weigh nitrosamine impurities at the time of purchase. (Mot. 2). This assertion misstates Dr. Keller's testimony, clipping a partial, mid-sentence quotation while ignoring the six accompanying pages of testimony in which Dr. Keller explains that her consumer valuation framework applies regardless of whether the specific information at issue comes to light before

[3] Plaintiffs point to the number of times that Dr. Keller's report uses the terms "likely", "may", and "might" in an attempt to paint Dr. Keller's opinions as "unsupported speculation." (Mot. 6, nn.4-6). But this is not an indication of any speculation. Dr. Keller's core opinion, which is firmly supported by the literature and research that she cites, is about illustrating the *range* of responses that can be expected from consumers (as in, one consumer "may" respond in one way, while another "might" respond differently).

or after the date of purchase. (*See* Keller Dep. 148:18-154:23). Dr. Keller's central point is that consumers in the healthcare context value products in a highly individualized, multi-faceted manner, and her framework recognizes that consumers can and do weigh the benefits of effective therapeutic value against risks—regardless of whether those specific risks are known at the time of purchase or come to light later. (Keller Rep. ¶¶ 39-41). The relevant question is not what a consumer knew at the time of purchase, but how new information supplied after purchase impacts individual valuations of a product that has already provided known therapeutic benefits to that customer.

Further, Dr. Keller's opinions are grounded in real-world evidence demonstrating how consumers *actually* assess and value perceived product risks allegedly associated with medications. One of Dr. Keller's real-world examples is the prescription drug Accutane, which was at the center of decade-long litigation based on the disputed allegation that it caused inflammatory bowel disease. (*Id.* ¶ 38). Dr. Keller explains that, despite the alleged potential for serious side effects associated with Accutane, consumers who choose to take it consider its benefits (reduction in acne) to outweigh the potential costs (negative health side effects), and therefore the drug has an overall net positive value for those individual consumers despite the presence of a negative feature. (*Id.* ¶ 39).

Plaintiffs criticize this example because the risks associated with Accutane

were disclosed to patients. (Mot. 3). This argument misses the point. Accutane illustrates the real-world flaw in Plaintiffs' theory that the alleged presence of trace impurities would necessarily wipe out *all* value in a medication. That is not how consumers actually behave. Even when consumers have knowledge of very serious potential risks associated with medications used to treat much less serious conditions than high blood pressure, some still choose to purchase the medications based on their therapeutic benefits. In short, *many consumers assign significant value to therapeutic benefit even in the face of significant known or perceived risks*.

Plaintiffs also fail to respond to other real-world evidence presented by Dr. Keller, such as consumer behavior in purchasing and consuming bacon. (Keller Rep. ¶¶ 53-55). A single serving of bacon is known to contain NDMA at levels about 50% higher than the FDA's acceptable limit for VCDs. (*Id.* ¶ 53). Consumers who enthusiastically purchase and eat bacon despite its known nitrosamine levels may well have a risk tolerance for comparable level of nitrosamines in VCDs without a reduction in perceived value. (*Id.*). This example also demonstrates why regular consumers of bacon who used VCDs may have continued to value the VCDs that they used upon learning of the nitrosamine impurities in certain VCDs. By contrast, the same information may have had a very different effect on the value assigned to VCDs by a patient who seeks to minimize his or her overall nitrosamine consumption. (*Id.* ¶¶ 53, 54). The same analysis applies to Plaintiffs and other

consumers who smoke or consume other products with known carcinogenic health risks. (*Id.*)

Dr. Keller's salient, real-world examples of informed consumers choosing to purchase and use products with potential health risks reliably support her opinions and negate Plaintiffs' purported "common sense" grounds for exclusion of her testimony.

C. Plaintiffs Mischaracterize Dr. Keller's So-Called "Assumptions" Regarding Consumer Choice.

Plaintiffs further mischaracterize Dr. Keller's opinions by attributing to her false "assumptions" that consumers faced a choice to purchase "adulterated" VCDs or no VCDs at all, and that consumers would "want to unnecessarily ingest carcinogens" by choosing, in a hypothetical world, to purchase VCDs with known nitrosamine impurities. (Mot. 5, 7). Dr. Keller's opinions are not premised on either supposed "assumption."

As an initial matter, Dr. Keller expressly rejected Plaintiffs' suggestion, at her deposition, that her assessment of product value is based on a consumer "choice" measured at the moment of purchase. (*See* Keller Dep. 157:22-159:22). Rather, Dr. Keller's valuation framework asks how consumers, now knowing what they did not know at the point of purchase, would value the VCDs that they already purchased and took. (*See id.*) It is, in short, a retrospective analysis that assesses the value of an impure VCD from the standpoint of a consumer who purchased it, used it, and

then learned of the impurity.

The same basic flaw undermines Plaintiffs' strawman argument that Dr. Keller improperly assumes that putative class members would affirmatively *want* to ingest alleged potential carcinogens. Dr. Keller has never opined or suggested that some consumers would "want" to ingest impure VCDs. Her point, rather, is that consumers who purchased, took, and received the full therapeutic benefit of Defendants' VCDs, and thereafter learned that the VCDs contained trace impurities, would not uniformly reassess the value of the VCDs to zero. According to Dr. Keller, these consumers would instead incorporate the new information into their existing decision-making frameworks and make individualized value assessments. (*See, e.g.*, Keller Rep. ¶¶ 24-26). And various consumers—weighing the benefit of, for example, heart attack prevention against the low risk of ingesting trace amounts of nitrosamine impurities—may assign no economic impact or minimal impact to the ingestion of such trace impurities. (Keller Rep. ¶ 30 n.46).

D. Dr. Keller's Opinions Are Reliable Without A Consumer Survey Or Conjoint Analysis.

Plaintiffs also argue that Dr. Keller's opinions are unreliable because she did not perform a conjoint analysis or conduct an independent consumer survey to confirm the value of VCDs to consumers. (Mot. 10). No such analysis or survey was necessary. Dr. Keller testified that she "frequently" conducts surveys and empirical studies outside the context of litigation (Keller Dep. 15:19-22), but that she did not

in this case because she "felt that there was evidence from consumers as well as literature from consumers that were sufficient to support [her] opinions." (*Id.* 42:3-9). This is an entirely appropriate approach under Rule 702.

It is well-settled that an expert may form conclusions by extrapolating from existing data and is not required "to base [her] opinions on independent data collection or field research[.]" *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 514 (3d Cir. 2005); *see also Rhoads Indus. v. Shoreline Found., Inc.*, No. 15-921, 2021 U.S. Dist. LEXIS 124066, at *22 (E.D. Pa. July 2, 2021) ("[T]rained experts commonly extrapolate from existing data, and it is acceptable for them to do so, provided that there is not too great an analytical gap between the data and the opinion proffered.") (quoting *GE v. Joiner*, 522 U.S. 136, 146 (1997)) (internal quotations omitted). Dr. Keller formed her opinions based on her review of existing data—literature, deposition testimony, empirical studies, other consumer surveys, and observed consumer behavior in the marketplace—and her opinions are reliable without any independent data collection.

Plaintiffs' disagreement with Dr. Keller's valid methodological choice to rely on existing data, rather than undertaking a conjoint analysis or consumer survey, is properly addressed through "vigorous cross-examination" since it goes to the weight, rather than admissibility, of her testimony. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993); *see also Leonard v. Stemtech Int'l Inc.*, 834

F.3d 376, 391 (3d Cir. 2016) (disagreements regarding expert's methodology and underlying assumptions "go[] to the weight given to his testimony, rather than admissibility"); *U.S. ex rel. Penelow v. Janssen Prods., LP*, No. 12-7758 (ZNQ) (LHG), 2022 U.S. Dist. LEXIS 4282, at *26 (D.N.J. Jan. 10, 2022) (same); *N.J. Dep't of Envtl. Prot. v. Amerada Hess Corp.*, No. 15-6468 (FLW) (LHG), 2019 U.S. Dist. LEXIS 146336, at *28 (D.N.J. Aug. 28, 2019) (similar).

Plaintiffs also cite a footnote from an unrelated court ruling suggesting that Dr. Keller testified in that case that "empirical testing is always required" to state a valid expert opinion. (Mot. 10 (citing *California v. Johnson & Johnson*, No. 37-2016-17229-CU-MC-CTL, 2020 WL 603964, at *21 n. 26 (Cal. App. Super. Jan. 30, 2020)). That is not the case. Dr. Keller's statement was made in the context of opining that the plaintiffs in that litigation, who had the burden of proof, had not established that consumers were likely to be deceived by the specific advertisements at issue in that case. Here, by contrast, Defendants do not have the burden of proof—and Plaintiffs, who do have the burden of proof, did not perform any empirical testing. Regardless, Dr. Keller need not "negat[e]" Plaintiffs' claims with affirmative, empirical testing and may instead "point out deficiencies in plaintiffs' proof." *Sanders v. Rosenberg*, Civil Action No. 06-1406 (NLH), at *16 n.3 (D.N.J. Apr. 10, 2008); *see also In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018) (finding it "entirely appropriate" that defendants'

experts' opinions "were, essentially, critiques of Plaintiffs' experts' evidence, methodologies, and conclusions.").

For all of these reasons, Plaintiffs' attacks on the reliability of Dr. Keller's methodology are baseless and should be rejected.

II. DR. KELLER'S OPINIONS ARE BASED ON REAL-WORLD EVIDENCE, INCLUDING PLAINTIFFS' OWN TESTIMONY AND THE FDA'S AND PHYSICIANS' DIRECTIONS TO PATIENTS.

Plaintiffs next attack the reliability of the real-world evidence cited by Dr. Keller as additional support for her opinion that individual consumers would value the health benefits they received from Defendants' VCDs, including: (i) putative class representative testimony admitting to the efficacy and value of Defendants' VCDs; (ii) FDA guidance after the valsartan recall that patients should continue taking their valsartan until they could obtain a replacement; and (iii) FDA's setting of acceptable intake limits for NDMA/NDEA. (Mot. 10-12). The entire premise for Plaintiffs' criticism is that Dr. Keller "inappropriately conflates concessions of the drugs' efficacy to economic value." (*Id.* 11). But that is the very crux of the disagreement between Dr. Conti and Dr. Keller: Dr. Conti believes VCDs' therapeutic benefits have *no* economic value, whereas Dr. Keller believes individual consumers may assign *significant* economic value to VCDs' therapeutic benefits. These are, at best, questions of weight, not admissibility. *See Leonard*, 834 F.3d at 391. Moreover, the weight of the evidence is on Dr. Keller's side.

First, Dr. Keller's opinions that therapeutic benefits had positive value to consumers are reliably based on the deposition testimony in this case. Plaintiff Samuel Cisneros, for example, testified that [redacted] (Exhibit C, Cisneros Dep., 100:9-10). That aligns with Dr. Keller's foundational opinion that consumers *do* place value on the therapeutic benefits received.

Plaintiffs respond to this and similar testimony from multiple other Plaintiffs by asserting that these same Plaintiffs also said they would not have purchased VCDs had they known of the impurities. (Mot. 11, Ex. 9). But that merely reinforces Dr. Keller's opinion that consumers have variable responses to new information. The fact that a party litigant believed that his/her VCDs had therapeutic value when he/she took them, but in hindsight claims he/she would not have purchased them if aware of the alleged risks simply highlights the variability of consumer reactions to new information. Dr. Keller testified to this exact point:

> Value equals benefit minus cost. They're acknowledging there was therapeutic benefit. That means something positive. Even if some of them are acknowledging that there is no economic value, one cannot assume that the sum or the difference between all of their benefits and costs would equal not only uniform, but would equal zero. * * * My assertion is that there are benefits and costs that need to be assessed in order to make a determination of worth, and therapeutic benefit is one example of benefit.

(Keller Dep. 217:6-218:14). In other words, consumers "do not make value assessments in a vacuum[.]" (Keller Rep. ¶ 31).

Second, Plaintiffs disagree that the FDA's and physician groups' post-recall instructions that consumers continue taking VCDs indicates that Defendants' VCDs would hold some value to consumers, treating it instead as a "lesser of two evils" advisory. (Mot. 11). Putting aside that this is at best a disagreement over the weight and import to assign to these public statements, it does nothing to undercut Dr. Keller's point that economic value is multi-factorial and non-binary. The fact that the FDA and physician groups found value in impure VCDs post-recall suggests that individual consumers are equally capable of assigning value to impure VCDs due to their health benefits such as heart attack prevention.

Third, Dr. Keller cites the FDA's setting of acceptable intake ("AI") levels to show that the presence of nitrosamines does not automatically render a drug "worthless" and to explain why value should be examined through the lens of the demand curve. Plaintiffs assert this indicator of value should be ignored because they intend to prove that "[l]iterally all" of Defendants' VCDs contained NDMA or NDEA. (Mot. 12). But this argument does not respond to Dr. Keller's point that the existence of AIs reflects that nitrosamine impurities—even if proven to be present at some level in all of the VCDs at issue—does not render all of those VCDs "worthless." Plaintiffs also argue that "Dr. Keller is simply not qualified to opine on the interpretation of FDA regulatory actions[.]" (*Id*.) Dr. Keller, however, is not offering a regulatory opinion; she is offering a value opinion from the perspective of

consumer behavior. The fact that the FDA set AI levels at which consumers may still purchase and ingest VCDs that contain impurities demonstrates that "the value of a treatment is not binary depending on the presence or absence of a nitrosamine impurity." (Keller Rep. ¶ 59). The existence of FDA-sanctioned AI limits is messaging that individual consumers can incorporate into their retrospective valuation judgments. (*See, e.g.*, Keller Dep. 67:6-9 ("[S]ome consumers may pay attention to the information or approval from the FDA as part of the messaging that they consider, and some may not.")).

In short, the evidence cited by Dr. Keller supports her opinions.

III. DR. KELLER DOES NOT IGNORE FACTS RELEVANT TO HER OPINIONS REGARDING CONSUMER BEHAVIOR.

Plaintiffs also contend that Dr. Keller made several "admissions" at her deposition that purportedly demonstrate her "blind[ness] to the most salient facts of the case." (Mot. at 5). But Plaintiffs concocted these supposed "admissions" by asking Dr. Keller questions at deposition about subjects totally unrelated to her underlying opinions on consumer behavior. These subjects include Dr. Keller's subjective familiarity with sales data for ZHP valsartan after the recall (*id*. 13-14); specific FDA labeling guidelines (*id*. 5), the substitutability of generic drugs (*id*. 6), and the contents of the U.S. Code (*id*. 7-8), all of which—as set forth below—pertain to regulatory, legal, and other matters unrelated to consumer behavior, consumer

valuation, or the reliability of Dr. Keller's methodology. [4] As a result, Dr. Keller's purported admissions that she does not have in-depth familiarity with these subjects is irrelevant to the admissibility of her opinions. *See 360Heros, Inc. v. GoPro, Inc.*, No. CV 17-1302-LPS-CJB, 2021 WL 5050879, at *3 (D. Del. Nov. 1, 2021) (rejecting motion to exclude expert who did not have knowledge of the patent at issue in the case because such information was not necessary for the expert to form his opinion on plaintiff's products and market alternatives).

A. Post-Recall Sales Data For ZHP's Products Are Irrelevant To The Reliability Of Dr. Keller's Opinions.

Plaintiffs argue that Dr. Keller failed to consider ZHP's post-recall decline in sales, which they claim is evidence of how the "market actually responded" to "information" regarding the "adulteration" of VCDs. (Mot. 13-14). According to Plaintiffs, "Dr. Keller had no explanation" for this so-called "market reaction" and "was surprised to learn that ZHP was placed on FDA import alert meaning that the sale of its products in the U.S. was illegal." (*Id.*) As an initial matter, the very testimony from Dr. Keller that Plaintiffs cite for this proposition in their briefing

[4] Plaintiffs' assertion that Dr. Keller is unfamiliar with testimony provided by corporate representatives of manufacturers and pharmacies about the sale of adulterated and/or misbranded drugs is similarly irrelevant because Defendants' VCDs *were* FDA-approved to be legally sold at the time of purchase. In any event, Dr. Keller's opinions concern *consumer behavior*; accordingly, the testimony from corporate representatives about corporate purchasing policies has no bearing on her opinions.

demonstrates that Dr. Keller was well aware ZHP products could not be sold in the United States after the recall. (Keller Dep. 184:8-18). And a decline in ZHP sales after the Company withdrew its VCDs from the market is not "real world evidence" of a consumer-driven market "reaction," as Plaintiffs claim. Indeed, it is not a consumer response at all; it is just the consequence of ZHP removing its product from shelves. Post-recall sales data of a product that is no longer sold is irrelevant to whether consumers would retrospectively assign zero value to the VCDs they previously purchased and used. Nor does such information render Dr. Keller's opinions unreliable with respect to how consumers would retrospectively view their purchases in light of new information about nitrosamine impurities and their perceived risks.

B. Dr. Keller's Knowledge Of Federal Law Is Not Relevant To The Reliability Of Her Opinions.

Plaintiffs also claim that Dr. Keller "ignores both the law and fact that adulterated and/or misbranded drugs cannot be lawfully sold in the first place." (Mot. 7). Dr. Keller has offered no opinions regarding when a drug may or may not lawfully be sold. Her opinions relate to how consumers assess information. Whether a drug could, in retrospect, be statutorily considered "adulterated," "misbranded," and/or "unlawful" to sell is, from a consumer valuation standpoint, simply new information consumers may (or may not) individually consider in reassessing the value of VCDs they lawfully purchased and used at the time of sale. The fact that

Defendants voluntarily withdrew VCDs from the market certainly affected the market availability of the VCDs going forward, but it does not imply the complete negation of value by consumers retrospectively incorporating new information into their value assessments. Plaintiffs are free on cross examination to question Dr. Keller's view on how consumers account for such information, but that does not render her opinions unreliable or inadmissible.[5]

IV. DR. KELLER IS QUALIFIED TO CRITIQUE DR. CONTI'S OPINIONS AND DID NOT "AFFIRM" THEM.

Finally, Plaintiffs argue that: (1) Dr. Keller is not qualified to critique Dr. Conti's damages theory because she is not an economist; and (2) even if she were qualified, Dr. Keller "affirmed Dr. Conti's approach, admitting that if there was no supply, then all consumers […] would end up 'paying no money for [Defendants' VCDs]' and that there would be 'no intersection of supply and demand[.]'" (*See* Mot. 15-16). Neither argument has merit.

First, Plaintiffs' conclusory assertion that Dr. Keller is "not qualified to critique the *economics* theory underpinning Dr. Conti's analysis" because she is an

[5] Plaintiffs make other statements that are just incorrect. For example, Plaintiffs state, "Dr. Keller never examined at issue VCDs FDA-approved labeling." (Mot. 5). The cited testimony relates to one specific valsartan label marked as an exhibit at her deposition, which Dr. Keller testified that she had not seen. (Keller Dep. 199:6-201:4; Dep. Ex. 9). But Dr. Keller expressly testified earlier in the deposition that she had "looked at some labels of valsartan," and she did not specifically know if the labels she reviewed "are FDA-approved or not." (Keller Dep. 73:20-22).

expert in "marketing" is baseless. (Mot. 1). Dr. Keller specifically and credibly rejected Plaintiffs' efforts to cast marketing and economics as "separate and distinct" disciplines, explaining that marketing combines multiple disciplines, including economics, and testified that she not only has a degree in economics and has spent more than four decades studying consumer behavior, but has published specifically in the field of behavioral economics. (Keller Dep. 21:22-23:1, 28:2-18). Dr. Keller is more than qualified to opine on the economics underpinning Dr. Conti's analysis, and the factfinder can decide how much credibility to give Dr. Keller's testimony as it pertains to her well-qualified criticisms of Dr. Conti. *See Maldonado v. Apple, Inc.*, No. 3:16-cv-04067-WHO, 2021 U.S. Dist. LEXIS 92483, at *85-87 (N.D. Cal. May 14, 2021) (rejecting motion to exclude opinions of marketing expert offered to rebut opinions of plaintiffs' experts' damages opinions; the expert was trained in consumer behavior, including the interplay between marketing and economic factors, "has at least some experience in behavioral economics," and "need not be so hyperspecialized as to be, for instance, a macroeconomist who specializes in the interaction of supply and demand" to address plaintiffs' damages theory); *see also Pineda v. Ford Motor Co.*, 520 F.3d 237, 245 (3d Cir. 2008) ("[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.") (quoting *Holbrook v.*

Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996)).

Second, Plaintiffs' argument that Dr. Keller admitted at her deposition that Dr. Conti's damages model is accurate because, if VCDs were not available on the market, consumers would not have paid anything for them is wrong. (*See* Mot. 15-16). For one thing, Plaintiffs mischaracterize Dr. Keller's testimony, which Plaintiffs' counsel elicited by asking about a post-recall scenario in which there was "no supply after the recall." (Keller Dep. 197:22-23). Dr. Keller agreed that in such a zero-supply scenario, consumers would end up "paying no money" for VCDs that were no longer being supplied after the recall. *Id*. That does not "affirm" Dr. Conti's approach; nor does it negate Dr. Keller's approach. Dr. Keller's opinions pertain to the value of VCDs that *were* supplied and that *were* paid for by consumers—the converse of Plaintiffs' scenario. The relevant inquiry, from Dr. Keller's perspective, is how individual consumers would value the VCDs they already purchased and used in light of new information. Plaintiffs falsely insist that Dr. Keller is "grafting her own marketing and behavioral science concepts onto Dr. Conti's economic theory-based analysis." (Mot. 15). But Dr. Keller's framework, as she explained at length, is not driven by Dr. Conti's putative negation of the so-called "legitimate supply" curve, and indeed rejects that approach in favor of determining how new information impacts the actual demand curve for each consumer. (Keller Rep. ¶¶ 71-73). Thus, far from an affirmation, Dr. Keller's approach refutes Dr. Conti's litigation-driven,

one-size-fits-all model. (*Id.* ¶ 74).

Plaintiffs' and Dr. Conti's disagreement with Dr. Keller is, at most, a proper subject for cross-examination. "What is presented here is a classic battle of the experts over disputed facts, to be settled by the finder of fact; it does not affect admissibility." *Dzielak v. Whirlpool Corp.*, No. 12-0089, 2017 WL 1034197, at *26 (D.N.J. Mar. 17, 2017); *see also e.g.*, *In re Gabapentin Patent Litig.*, No. 00-2931, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that defendants' critiques of plaintiffs' experts' methodology and inconsistent conclusions presented "a battle of the experts, and both sides will be permitted to present expert testimony on these issues and to cross-examine the other side's expert witnesses.").

CONCLUSION

For foregoing reasons, Plaintiffs' Motion to Exclude the Testimony of Dr. Keller should be denied.

Dated: June 2, 2022

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CERTIFICATE OF SERVICE

I, Tiffany M. Andras, an attorney, hereby certify that on June 2, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

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